ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States House of Representatives

COMMITTEE ON ENERGY AND COMMERCE 2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6115

> Majority (202) 225-3641 Minority (202) 225-2927

February 22, 2023

Mr. Kemp Chester Senior Advisor, International Relations and Supply Reduction White House Office of National Drug Control Policy 1600 Pennsylvania Avenue NW Washington, D.C. 20500

Dear Mr. Chester:

Thank you for appearing before the Subcommittee on Health on Wednesday, February 1, 2023, to testify at the hearing entitled "Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Wednesday, March 8, 2023. Your responses should be mailed to Jolie Brochin, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Jolie.Brochin@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,
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Brett Guthrie

Chair

Subcommittee on Health

Attachment 1—Additional Questions for the Record

The Honorable Cathy McMorris Rodgers

- 1. According to the Government Accountability Office (GAO), the 2022 Office of National Drug Control Policy's National Drug Control Strategy does not comply with certain statutory requirements. For example, the Strategy is required to contain a systematic plan for increasing data collection, including to enable real time surveillance of drug control threats. However, as of December 2022, ONDCP has not created such a plan. What is the timeline ONDCP has established for creating and implementing this plan?
- 2. What percent of ONDCP staff work in person five days per week? What percentage of meetings are held virtually versus in-person?

The Honorable Greg Pence

The opioid and Fentanyl crisis is having a devastating impact on families across my district. State and local law enforcement agencies in Indiana's Sixth Congressional District are on the front lines, and they consistently communicate to me that they are overwhelmed by the illicit drugs flooding our community. According to the CDC, "there were an estimated 100,306 drug overdose deaths in the United States during the 12-month period ending in April 2021, an increase of 28.5% from the 78,056 deaths during the same period the year before." Our state and local partners need more resources to combat the ruthless cartels that are trafficking illicit drugs across our southern border and killing family members, friends, and neighbors in our communities.

1. How can federal law enforcement agencies, such as the DEA, leverage their resources to more closely coordinate with local law enforcement agencies to increase the detection and prevention of illicit drugs in Hoosier communities?

We know these violent cartel criminals are intentionally altering the chemical structure of prescription-grade Fentanyl to create synthetic opioids with the intention to evade federal law enforcement.

2. How do you think drug traffickers weigh the legal risks of using specific synthetic Fentanyl analogues and how can our federal law enforcement agencies best hold these criminals accountable for their actions?

The Honorable Dan Crenshaw

- 1. How would ONDCP respond to proposals of an expedited approval process for fentanyl-related treatments/Opioid Use Disorder treatments given the enormity of the fentanyl problem?
 - For context--One of the concerns is legislative language that deems any fentanyl-related substance Schedule 1. The DEA passed an edict a few years back designating anything that looked like fentanyl to be a Schedule 1 substance although fentanyl itself is Schedule II. What we don't want is unnecessary restraint in the ability to conduct research and develop therapeutics (or the potential fentanyl vaccine). For example, there is ample evidence that research on hapten, a fentanyl-like molecule, has no biological activity related to fentanyl-induced effects (e.g. analgesia). The hapten, in simple terms, is the "backbone" of the fentanyl molecule that is also common to fentanyl derivatives. How would the designation apply to fentanyl type molecules.
- 2. How important is additional funding for future fentanyl-related research to the work being done by ONDCP; and, if appropriated, how would they prioritize directing that funding?

The Honorable Frank Pallone, Jr.

- 1. We on this subcommittee remain committed to addressing the opioid crisis. Illicit fentanyl and fentanyl-related substances remain a critical threat to the public health and safety of our country. According to the CDC, over 150 people continue to die daily from fentanyl overdoses. A refresher on some of the nuances of fentanyl would be helpful. Can you briefly remind us of the differences between Fentanyl, Fentanyl-Related Substances (FRS), and Fentanyl analogues?
- 2. Does the proposal to permanently schedule FRS change the current classification of fentanyl if used and regulated for medical purposes?
- 3. How many FRS have we encountered? Does chemical structure alone determine the pharmacological effect of an FRS?
- 4. Are the rates of fentanyl-related deaths continuing to increase?
- 5. Research and evidence-based approaches are a key component of the president's proposal on how to address FRS. In order to conduct quality research, investigators need access to fentanyl analogues as they might be useful in enhancing current treatments or developing new ones. A key component of the Administration's proposal involves how FRS are classified or subsequently reclassified if found to have a lower-risk profile. Can you explain the importance of the provision for "off-ramping" an FRS?
- 6. How would off-ramping assist researchers and science?

- 7. What is your understanding of how the current administration's proposal differs from the HALT Fentanyl approach?
- 8. How did the Administration consult with external stakeholders and what was their response to the Administration's proposal?
- 9. How does the administration proposal change mandatory minimum penalties for offenses involving fentanyl-related substances?
- 10. To your knowledge, how many Schedule I fentanyl-related substance trafficking offenses have been pursued since the temporary scheduling order has been in place?
- 11. Can you describe novel approaches in Dr. Gupta's inaugural National Drug Control Strategy and why it is critical to maintain robust resources for these activities?
- 12. The Biden Administration's proposal to address FRS exempts those charged with an FRS offense from quantity-based mandatory minimum penalties, unless the offense results in death or serious bodily injury. Is there any indication that permanent scheduling of FRS, with exemptions for quantity-based mandatory minimums, will lead to an increase in new FRS being created?